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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,847	10/02/2003	John Staniforth	541.1027con	5127

7590

08/10/2005

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EXAMINER

BERKO, RETFORD O

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/677,847

Applicant(s)

STANIFORTH, JOHN

Examiner

Retford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Acknowledgement: The Information Disclosure-Statement filed 2 17, 2004 is acknowledged.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No.6, 660, 303. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn toward a method for improving compressibility of a superdisintegrant by enhancing the hydrophobicity of the superdisintegrant (amylopectin) through addition of an

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augmenting agent such as surfactant, binder or lubricant. The instant claims are also drawn toward improving the compressibility of a superdisintegrant by adding an augmenting agent.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn toward the same invention in Patent '303 wherein addition of an augmenting agent such as a surfactant to a disintegrant increased the hydrophobic boundary or barrier at the cellulose surfaces and thereby lead to enhanced compressibility of the cellulose during granulation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 90-100 are rejected under 35 U.S.C. 102(b) as being anticipated by Staniforth et al (US 5, 741, 524).

Staniforth et al (Patent '524) teaches a sustained drug formulation wherein a surfactant is employed to augment the compressibility of a superdisintegrant, i.e. microcrystalline cellulose in making tablets comprising biologically active agent (abstract, col 26, lin 40-60 and col 27, lin 55-60).

Claims 90-100 are anticipated by Patent '524.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-89 are rejected as unpatentable under 35 U.S.C. 103(a) over Staniforth et al (US 5, 741, 524) in view of Cartillier et al (WO 91/16043).

Staniforth et al (Patent '524) discloses a sustained drug formulation wherein a surfactant is employed to augment the compressibility of a superdisintegrant, i.e. microcrystalline cellulose in making tablets comprising biologically active agent (abstract, col 26, lin 40-60 and col 27, lin 55-60). According to Staniforth, augmenting agent such as silicon dioxide or surfactant such as sodium lauryl sulfate when added to microcrystalline cellulose creates hydrophobic boundary at the cellulose surfaces (col 7, lin 65, continuing to col 8, lin 1-15) improving the compressibility of the disintegrant (col 9, lin 23-30 and col 10, lin 47-55).

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Staniforth does not teach the method or process for improving compressibility of a superdisintegrant, does not teach amylose/amylopectin or the use of lubricant and binder specifically as the compressibility improving agents (i.e. only mentioned as additional ingredient; col 18, lin 36-45).

Cartillier et al (Patent '589) disclose preparation of disintegrant--cross-linked cellulose; and the use of amylase as binder, disintegrant and lubricant for enhancing the disintegration properties of the disintegrant (col 4, lin 28-32; lin 53, lin 66 and col 5, lin 5-10; lin 59, continuing to col 6, lin 1-10; Table 1 and col 8, lin 30-45).

One of ordinary skill would have been motivated to devise a method of augmenting the disintegrating properties of disintegrants by co-pressing microcrystalline cellulose and a compressibility augmenting agent together as a dry mixture for making sustained release tablets (Patent, '524, col 14, lin 38-45 and col 18, lin 36-44). Because Staniforth disclosed that adjuvants or ingredients such as lubricants, binders and glidants provide desirable formulation effects in sustained release (Patent '524, col 18, lin 36-44), one of ordinary skill would expect that by combining these adjuvants with disintegration enhancing effects in drug formulation would increase the disintegration time for the drug irrespective of the solubility of the active agent. Therefore, the invention as a whole would have been obvious to one of ordinary skill at the time that it was made.

The following prior art, is cited as relevant to applicant's claims, but is not currently relied upon for the rejections:

Gebhard-Hansen et al (US 6, 036, 975): The prior art explains what the designation "superdisintegrant" means and the amounts of a disintegrant required for use in order to qualify

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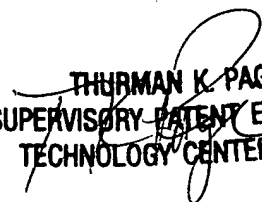
as a "superdisintegrant" (see Patent '975, col 1, lin 50-67, continuing to col 2), lin 1-30) and the use of the superdisintegrant in a tablet formulation. The reference is currently not relied upon because it does not provide a method of enhancing the compressibility of the disintegrant.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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